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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/560,263

06/23/2006

Barry Dean Briggs

38187-2804.US

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77845

7590

06/08/2010

Goodwin Procter LLP

Attn: Patent Administrator

135 Commonwealth Drive

Menlo Park, CA 94025-1105

EXAMINER

EISEMAN, ADAM JARED

ART UNIT

PAPER NUMBER

3736

MAIL DATE

DELIVERY MODE

06/08/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/560,263	Applicant(s) BRIGGS ET AL.	
	Examiner ADAM J. EISEMAN	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-15,32,34-37 and 41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-15,32,34-37 and 41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :12/9/2005,3/16/2007,4/2/2007,4/22/2008,6/11/2008,6/30/2008,8/26/2008,11/05/2008,12/31/2008,3/20/2009,5/22/2009,9/14/2009,12/10/2009,1/26/2010,3/12/2010.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of group I (claims 7-15, 32, 34-37 and 41) in the reply filed on 2/26/2010 is acknowledged.

Information Disclosure Statement

2. The information disclosure statements (IDS) submitted on 12/9/2005, 3/16/2007, 4/2/2007, 4/22/2008, 6/11/2008, 6/30/2008, 8/26/2008, 11/05/2008, 12/31/2008, 3/20/2009, 5/22/2009, 9/14/2009, 12/10/2009, 1/26/2010, 3/12/2010 were received and placed in the record on file. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 13-15 and 41 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. The term "levels below that of known devices" in claims 13-15 is a relative term which renders the claim indefinite. The term "levels below that of known devices " is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Claiming that the pain level is below that of known devices

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is indefinite as we do not know the pain level of such known devices and there are many known devices thus the examiner has no idea as to which devices pain level we are comparing the claim to. Furthermore, pain itself is a relative term dependant on the user, and cannot be quantified unless it is referred to by a metric, none of which have been established in the claim or specification.

6. Claim 41 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: in the final limitation of the claim the applicant states “using the linear motion of the slider to rotate the cartridge, **punch open a new cavity** and load a new penetrating member.” The claim omits the essential relationship of where the new cavity is punch and what is used to punch the new cavity. Without the relationship described it is unclear as to where the cavity is punch and what is punching the cavity. Without the essential structural relationship the examiner cannot examine the claim due to its indefiniteness.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 7-12 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simons et al (US 5,971,941) in view of Lum et al (US 2002/0042594).

Simons discloses a device for body fluid sampling usable with a cartridge housing a plurality of penetrating members (column 5, line 45 – column 9, line 61), the device comprising: a housing (figures 6 and 7); a penetrating driver couple to said housing and for use with said cartridge (column 9, line 63 – column 12, line 29); wherein the penetrating member driver moves at least on of said penetrating members at velocities with conform with a velocity profile (column 9, line 63 – column 12, line 29); and a processor.

However, Simons does not disclose the processor is used for controlling the penetrating member driver along the velocity profiles.

Lum teaches the use of a processor used to control a penetrating member driver in order to move it along a desired velocity profile (paragraph [0023]).

Regarding claims 7-12 and 32; it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Simons cartridge based fluid sampling

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device use its processor for controlling the penetrating member driver as taught by Lum in order to move the penetrating member along a desired path and velocity profile.

Further regarding claim 8; Simons discloses a cartridge housing a plurality of penetrating members and a window allowing a user to see the cartridge while the cartridge is in said housing (see figure 7).

Further regarding claims 9-11 and 32; Simons discloses the device has a display for displaying any information about the status of the measurement (column 13, lines 4-31). It would have been obvious to one of ordinary skill in the art at the time of the invention that device status, lancing performance and lancing parameters are all information regarding the status of the measurement and lancing performed by the Simons/Lum device. Furthermore, it was well known in the art at the time of the invention to use screen savers on LCD displays to show inactivity and increase the LCD display life.

Further regarding claim 12; Simons discloses a single button for actuating the lancet along its path into and out of the tissue (column 13, line 57 – column 14, line 10).

Allowable Subject Matter

10. Claims 34-37 are allowed.

11. The following is a statement of reasons for the indication of allowable subject matter: Claims 34-37 disclose a device novel over the prior art for sampling body fluid using a cartridge and meter having a mechanism for advancing the penetrating members of the cartridge into a firing position, removing a sterility barrier from the cartridge to expose the penetrating member and firing/retracting the penetrating

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members from the cartridge. The prior art of record does not disclose a mechanism having the claimed structure for advancing the cartridge and for moving a sterility barrier located on the cartridge.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ADAM J. EISEMAN whose telephone number is (571)270-3818. The examiner can normally be reached on Monday-Friday 9:00 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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5/22/2010

/A. J. E./

Examiner, Art Unit 3736

/Max Hindenburg/

Supervisory Patent Examiner, Art Unit 3736